Bonebridge Health Related Quality of Life and Clinical Outcomes in New Zealand

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2020

A thesis submitted in partial fulfilment of requirements for the degree of Master of Audiology

Acknowledgements

To my wife and family – Thank you Lydia for being there for me this whole time. I wouldn't have been able to get through this year without your support. Thank you Mum for everything you have done for me, and I know this has been a difficult year for you. Thank you Dad for always being there to talk and provide me with encouragement when I'm worried things aren't going right.

To my supervisors – thank you Rebecca for being the best supervisor. You always provided help almost immediately. When things seemed impossible, a meeting with you made everything seem achievable again. I have always appreciated your remarkable work ethic and ability to schedule and manage time. You are the perfect role model for someone to aspire be. Thank you Phillip for being so approachable and so willing to answer all of my questions. It has been a very good experience working with you.

To my lecturers and educators – Thank you Rebecca (again), Greg, Alison, Jonny, Nicole and Ciara for teaching me everything that I now know about audiology.

To my classmates – Thank you all for the encouragement and support. Especially thank you for all the funny yarns.

Lastly, I would like to thank God for all that He has done.

Funding

The author discloses financial support for this thesis – This thesis was supported by a grant from Health Utilities Inc. (HUInc.) in the form of licensing to use the Health Utilities Index instrument.

Abstract

Objectives: To determine to what extent the Bonebridge improves clinical and health related quality of life outcomes in the New Zealand context.

Methods: Preliminary results for 18 adults with conductive and mixed hearing loss, and single sided deafness who have undergone Bonebridge implantation are presented. Ear-specific audiometric thresholds were obtained pre implantation. Aided sound field audiometric thresholds were obtained post switch-on. Unaided and aided speech discrimination scores (SDSs) were obtained 4 weeks post switch-on. Health related quality of life information was assessed using patient reported outcome measures. An in-house developed questionnaire and the SSQ12-B were administered at 6 and 12 months post switch-on. The Health Utilities Index questionnaire was administered at 12 months or greater post switch-on.

Results: The median intensity level at which participants obtained maximum SDS was significantly improved in the aided condition. The median half-peak level was significantly improved in the aided condition. The median SDS at 50 dB HL was significantly improved. SNR Loss score improved for 10 participants and an overall mean change score of 3.47 dB improvement in the aided condition was observed. HRQoL outcomes demonstrate high device usage, high ease of use and vocational performance, and perceived benefit in the speech, spatial and quality components of hearing.

Conclusions: Overall improvements were seen in both Clinical and HRQoL Measures. This study proposes the Bonebridge as a viable solution for managing hearing loss in this population.

Keywords: Bonebridge, clinical outcomes, quality of life, QoL, health related quality of life, HRQoL,

Contents

Abbreviations

AC	Air conduction
BC	Bone conduction
BCDQ	Bone conduction device questionnaire
BC-FMT	Bone conduction – floating mass transducer
BTE	Behind the ear [hearing aid]
CHL	Conductive hearing loss
CI	Cochlear implant
CROS	Contralateral routing of signal
HDEC	Health and Disability Ethics Committees
HPL	Half peak level
HRQoL	Health Related Quality of life
HUI	Health Utilities Index
MHL	Mixed hearing loss
NZ	New Zealand
NZAS	New Zealand Audiological Society
PI	Performance-Intensity
QoL	Quality of Life
RF	Radio frequency
SDS	Speech Discrimination Score
SNHL	Sensorineural hearing loss
SRT	Speech reception threshold
SSD	Single sided deafness

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Introduction

Hearing loss

Hearing loss occurs when there is reduced or absent auditory input to the brain. It can be divided into two main subcategories. They are conductive hearing loss, and sensorineural hearing loss. If these occur simultaneously, it is called a mixed hearing loss (American Speech Language Hearing Association, 2019).

Sensorineural hearing loss.

Sensorineural hearing loss (SNHL) describes hearing loss that originates at the inner ear, i.e. the cochlear, or the auditory nerve. Normally it cannot be treated medically and is therefore permanent (American Speech Language Hearing Association, 2019). The causes of SNHL include genetic factors, infectious diseases, noise exposure, age, and other pathological processes. It can affect one or both ears and can be congenital or acquired. Hearing loss that occurs in one ear only is called unilateral hearing loss. If a unilateral SNHL is un-aidable, it is often called single sided deafness (SSD).

Conductive hearing loss.

Conductive hearing loss (CHL) describes hearing loss that originates at the middle or outer ear. It can be congenital or acquired. The middle ear structures are important for the transmission of acoustic energy from the external auditory meatus to the oval window of the cochlea and are responsible for correcting the impedance mismatch between the outer ear and inner ear (Zwislocki, 1962). If there is a blockage or pathological process that interferes with either the outer ear or the middle ear, the result may be a CHL. CHL, unlike SNHL, can

sometimes be medically treated. Some causes include congenital defects, middle or outer ear infections, trauma, and ossification of the middle ear bones.

Prevalence

Statistics New Zealand | Tatauranga Aotearoa (2013) state that hearing loss affects 9% of the population of New Zealand based on a 2013 disability survey. Further, the percentage of New Zealanders affected by hearing loss is projected to increase (Exeter, Wu, Lee, & Searchfield, 2015). In the United States, Goman and Lin (2016) state that hearing loss effects 23% of Americans that are 12 years of age or older. From a global perspective, the World Health Organisation (2018) estimates that the global prevalence of hearing loss is 6.1%.

Impact of hearing loss

Psycho-social

There are many consequences of hearing loss. Some negative consequences include difficulty with communication, reduced interpersonal interaction, social isolation, mental health and psychological complications, relationship problems and poorer health related quality of life (Manchaiah & Stephens, 2013). Hearing loss can also result in third-party disability meaning that the friends and family of persons with hearing loss can be affected (Scarinci, Worrall, & Hickson, 2009).

Economic

Hearing loss can also have economic consequences for the people affected. Persons with hearing loss have increased health care related costs compared to persons with normal hearing (Reed et al., 2019). Further, persons with hearing loss may experience a lower earning potential compared to their normal hearing peers (Emmett & Francis, 2015). Hearing loss also has an economic burden on society. A systematic review by Huddle et al. (2017) found that, in the

United States, there is wide variance in the estimates of the economic burden of hearing loss that results due to lost productivity but that it is likely billions of dollars annually.

Health

Persons affected by hearing loss may have an increased risk to their personal safety (Manchaiah & Stephens, 2013). There is also a higher rate of hospitalization and re-admission for persons with hearing loss (Reed et al., 2019), compared with persons with normal hearing. Ultimately, persons with hearing loss may experience lower health related outcomes than persons with normal hearing (Chia et al., 2007).

Management of Hearing Loss

Non-device Rehabilitation.

Boothroyd (2007) describes the importance of not only improving auditory function using devices, but also the importance of instruction, counseling and perceptive training. He lists five categories regarding hearing loss that need to be addressed. They are anatomy and physiology, sensory function, activity, participation and Quality of Life (QoL). Where there is decreased cochlear integrity as a result of hair cell damage, anatomy and physiology cannot currently be addressed (Wan, Lovett, Warchol, & Stone, 2020). However sensory function can be addressed though devices and instruction. The activity, participation and QoL categories can be addressed through non-device interventions. Perceptual training, sometimes called auditory training, is an intervention that aims to enhances a person's existing ability to perceive auditory and visual input (Boothroyd, 2007), and has been shown to be effective in clinical settings (Rubinstein & Boothroyd, 1987; Sweetow & Sabes, 2006). Counselling, as separate from instruction, is an intervention that aims to improve participation and QoL by discussing the impact of hearing loss and developing techniques to overcome it's associated barriers

(Boothroyd, 2007), and has also been shown to be effective (Hawkins, 2005). Further, communication strategies form an important aspect of rehabilitation (Tye-Murray, 2018). Therefore, to achieve the best possible outcomes, it is important to address hearing loss with a range of non-device interventions including, instruction, counseling and perceptual training (Boothroyd, 2007),whether or not devices are used.

Air conduction devices.

Air conduction (AC) devices are well suited to providing amplification for SNHL. They are also able to provide amplification for CHL. Because this study is concerned with the Bonebridge, this section will be limited to the use of AC devices in the application of CHL, MHL and SSD, which are the intended applications for the Bonebridge (MED-EL, n.d.-b).

There are some situations where using AC devices are not optimal or are not able to be used for CHL. AC hearing aids increase the risk of developing infection in the middle and outer ear (Kadhim, Colreavy, O'Donovan, & Blayney, 2004; Mylanus, van der Pouw, Snik, & Cremers, 1998). Interventions that increase the risk of infection are not ideal because recurrent infections can damage inner ear structures which may lead to a decrease in cochlear reserve (Ricci et al., 2010). AC hearing aids also need high levels of gain to overcome CHLs. This can increase the likelihood of feedback occurring. Further, very large conductive components can result in less optimal audiological outcomes. This is discussed in the bone conduction devices section.

Regarding SSD, AC hearing aids have successfully been used for many years. The contralateral routing of signal (CROS) described by (Harford & Barry, 1965) is a technique to manage SSD. The aim of a CROS system is to eliminate the head shadow effect but acceptance is low in persons with normal hearing in the better ear (Harford & Dodds, 1966; Hol, Kunst,

Snik, & Cremers, 2010). The possibility of low acceptance highlights the importance of obtaining subjective outcomes when considering any device intervention.

Bone conduction devices.

Bone conduction devices stimulate the cochlear via the bone conduction mechanism which essentially bypasses the outer and middle ears. More precisely, the mechanism of bone conduction involves a complex assortment of skull vibrations (Stenfelt & Goode, 2005). The outer ear component involves vibration of the skull and cartilaginous portions of the external auditory canal and subsequent air conduction transmission (Steiger, 2015; Stenfelt & Goode, 2005). The middle ear component involves vibrations of the ossicles, out of phase with the skull vibrations, and subsequent transmission of energy to the oval window (Steiger, 2015). Lastly, with the inner ear component, which itself involves numerous mechanisms including distortion of the cochlea, fluid inertia, and transmission though fluid within the skull (Stenfelt & Goode, 2005; Tonndorf & Tonndorf, 1968). Soft tissue conduction was also described by de Jong et al. (2011). Ultimately, vibrations arrive at the cochlea via the inner, middle and outer ear mechanisms that cause displacement of cochlear fluid and initiate travelling waves in the basilar membrane (Steiger, 2015).

Although AC devices can be used to manage CHL, at some degree of conductive component it will become more efficient to transmit acoustic energy via the bone conduction mechanism rather than the AC mechanism. Several studies have reported the benefit of bone conduction devices for managing CHLs in certain situations when compared to air conduction devices. Mylanus et al. (1998) suggested that if the air-bone gap was greater than 25 - 30 dB HL, that a bone conduction device will provide better audiological outcomes when compared to analogue behind-the-ear (BTE) AC hearing aids. Advances in AC hearing aid technology have

meant that BTEs can now be used to adequately manage CHLs with larger conductive components than before. A more recent study by de Wolf, Hendrix, Cremers, and Snik (2011) suggested that the crossover point at which a bone conduction device will produce better audiological outcomes is an air-bone gap of 35 dB HL or greater. In addition to managing CHLs and MHLs, they can also be used to manage SSD by functioning as a transcranial CROS system (Fowler, 1960; Welling et al., 1991).

In some situations, bone conduction devices may provide additional advantages. Bone conduction devices do not occlude the ear canal which may be useful in a chronically discharging ear. Additionally, conditions such as aural atresia may preclude the use of air conduction devices all together, making bone conduction devices particularly useful. In some cases, bone-conduction devices may be the only viable option. A potential disadvantage of bone conduction devices, particularly surgically fitted ones, is the costs associated with surgery (Sardiwalla, Jufas, & Morris, 2017) which are not present in AC devices.

Active versus Passive.

Bone conduction devices can be classified as either passive or active. These terms may also be referred to as skin drive or direct drive respectively. Passive bone conduction systems have an external transducer that is in contact with the skin. The acoustic signal passes through the skin and tissue to the bone. The acoustic signal then stimulates the cochlea via the bone conduction mechanisms as described above. With active bone conduction systems, the transducer directly stimulates the bone. The acoustic signal then stimulates the cochlea via the bone conduction mechanisms.

Transcutaneous vs percutaneous.

These terms describe the way in which a signal, either acoustic or digital, is passed through the skin. A percutaneous system uses a hard connection that passes through a break in the skin. In a percutaneous system, the acoustic energy is transferred to the bone via the abutment, thus it is also an active system. Percutaneous systems are considered the 'gold standard' of bone conduction devices (Pittman, 2019a). They provide a better signal quality than soft-band devices (Pittman, 2019b). An example of an active percutaneous system is the Baha Connect System by Cochlear which uses a metal abutment. Oticon also manufactures a device in this category. Percutaneous systems carry a small risk of complications including infection, failure to osseointegrate, and damage due to trauma (Dun et al., 2012).

In contrast, a transcutaneous system has no hard connection and the acoustic or digital signal passes through the skin while leaving the skin intact. An example of a passive transcutaneous system is a soft-band bone conduction device. Another example is the Baha Attract System by Cochlear, which uses a magnet to correctly position a transducer above the implanted portion, and the acoustic signal is transferred transcutaneous through the skin to the implanted portion which is osseointegrated. However, transcutaneous devices are also not without drawbacks. These devices require adequate transducer power and a minimum magnetic or tension force to adequately transfer acoustic energy from the external transducer to the bone, which can sometimes cause inflammation, pain and headaches (Lustig et al., 2001). Further, soft tissue attenuation can reduce sound quality (Håkansson et al., 1990).

The term 'transcutaneous' can be used not only in the context of transferring acoustic energy but also for digital signals. A common example of a system that transmits a digital signal transcutaneously is a modern cochlear implant (CI) that uses a Radio Frequency (RF) link

between the inductor coils of the external and internal portions of the CI (Buchegger et al., 2005; Zeng, Rebscher, Harrison, Sun, & Feng, 2008). The Bonebridge uses this same principle.

The Bonebridge System

Description

The MED-EL Bonebridge is a "bone conduction implant system" that is indicated for CHL, MHL and SSD (MED-EL, n.d.-b). It has the benefit of being able to provide active bone conduction whilst being a transcutaneous system that leaves the skin intact. It consists of an external and internal portion. The external portion contains microphones and the sound processor and is held in place magnetically. The digital signal is transmitted transcutaneously to the implant via inductor coils. The internal (implanted) portion, shown in Figure 1, consists of a magnet that is used to secure the processor, inductor coil to receive the digital signal, a demodulator which is the 'electronics' of the internal portion and a bone conduction transducer called the Bone Conduction – Floating Mass Transducer (BC-FMT). The BC-FMT is fixed to the bone via two screws that are osseointegrated, and is positioned within the mastoid (MED-EL, n.d.-a), see Figure 2.

Figure 1. Model BC 601 implant. Photo credit: MED-EL (used with permission).

Figure 2. Representation of the Samba processor, BC 601 implant and anatomy.

Photo credit: MED-EL (used with permission).

Clinical Outcomes

On evaluation of the studies performed thus far, the Bonebridge has been found to produce positive audiological outcomes. A study looking at clinical outcomes by Riss et al. (2014) found that the Bonebridge produced good functional gain and speech perception in recipients that have BC thresholds of 45 dB HL or better. Another study by Wimmer et al. (2019) documented that the Bonebridge produced improved thresholds and word recognition results compared to unaided measures. Further, they suggest that the indication criteria for the Bonebridge device should be persons with BC thresholds of 38 dB HL or better in their better ear. Similarly, Weiss et al. (2017), Schmerber et al. (2017), and Skarżyński et al. (2019) documented significant improvement in speech perception in quiet and in noise after implantation with the Bonebridge.

Weiss et al. (2017) looked at clinical outcomes and patient acceptance of the Bonebridge. They reported that there were no surgical site infections in their study group. Further, using an adapted version of the Bern Benefit in Single Sided Deafness questionnaire, they found that overall, users reported a high level of acceptance and satisfaction with the Bonebridge. Schmerber et al. (2017) also reported good patient satisfaction with the Bonebridge, as well as good skin safety. Lassaletta, Calvino, Zernotti, and Gavilán (2016) found that Bonebridge implantation does not cause significant pain post-operatively, and the levels of pain are in line with other procedures such as CI implantation.

To date, only one study of the Bonebridge has been conducted in New Zealand (Kulasegarah, Burgess, Neeff, & Brown, 2018). These researchers looked at clinical outcomes in children with atresia and microtia. It is not fully known if the clinical improvements described

above are also seen in a New Zealand adult population. Therefore, the first goal of this study is to document clinical outcomes of the Bonebridge device in the New Zealand context.

Health Related Quality of Life Outcomes

The World Health Organization defines Quality of Life (QoL) as an "individuals' perceptions of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns". This concept is broad in its application and includes health, psychological, social and environmental domains (The Whoqol Group, 1998). Health Related Quality of Life (HRQoL) is a term with a narrower scope. Although there is no single agreed upon definition of HRQoL, in this thesis, it is defined as a person's physical and emotional well-being, their experienced quality of life, as affected by their health status (Busija et al., 2011; Karimi & Brazier, 2016).

There are several self-report tools available in audiology to assess HRQoL for hearing-related health conditions. Schmerber et al. (2017) used the Abbreviated Profile of Hearing Aid Benefit (APHAB; Cox & Alexander, 1995), the Glasgow Benefit Inventory (GBI; Robinson, Gatehouse, & Browning, 1996), and the International Outcome Inventory- hearing aids (IOI-HA; Cox & Alexander, 2002) questionnaires, where they also documented improvements. Skarżyński et al. (2019) also documented improvements via the APHAB following Bonebridge implantation.

The speech, spatial and qualities of hearing scale (SSQ) is a self-report tool that aims to be sensitive to not only the traditionally important speech component of hearing but also to the spatial components of hearing such as directionality and movement, as well as the quality components of hearing such as naturalness of sound and ability to distinguish multiple sources of sound (Gatehouse & Noble, 2004). The SSQ12, is a short form 12-question version that has been developed and is shown to produce similar results to the original 49-question SSQ (Noble,

Jensen, Naylor, Bhullar, & Akeroyd, 2013). A thesis by Cox (2016) demonstrated that the SSQ12 has good test-retest reliability.

Eberhard, Olsen, Miyazaki, Bille, and Caye-Thomasen (2016) used the SSQ12 questionnaire where they documented good self-reported ability in the quality component questions, but relatively poor ability in the sound localization component questions. Laske, Röösli, Pfiffner, Veraguth, and Huber (2015) used the SSQ-B (benefit version; Jensen, Akeroyd, Noble, & Naylor, 2009) in an SSD only cohort and document the most benefit in the speech component questions. They also documented some benefit in the spatial and quality component questions.

Hearing aid usage and frequency is widely considered to be an important outcome measure for rehabilitation and is associated with the benefit and satisfaction obtained from using a device (Cox & Alexander, 1999; Uriarte, Denzin, Dunstan, Sellars, & Hickson, 2005). In addition, a study with hearings aids found that there is a link between a person's dexterity and their ability to effectively use hearing aids (Kumar, Hickey, & Shaw, 2000). Further, hearing aid design factors can influence how easy a device is to mount and use (Erber, 2003; Meredith & Stephens, 1993). Therefore, it is important to obtain information about device frequency and duration of use, as well as ease of use when obtaining HRQoL data.

The Health Utilities Index (HUI®) is a system to derive single and multi-attribute level health utility scores and is a measure of HRQoL (Horsman, Furlong, Feeny, & Torrance, 2003). The HUI is a validated system to calculate quality adjusted life years (QALYs) which can then be used to evaluate the cost-effectiveness of an intervention (Furlong et al., 2012). Possible scores range from -0.36 indicating a state worse than death, to 1 indicating a state of perfect health. It appears that HUI data on the Bonebridge has not yet been published. As a point of interest,

(Monksfield, Jowett, Reid, & Proops, 2011) used the HUI mark 3 (HUI3), which is sensitive to changes in hearing and language, to calculate QALYs and subsequent cost effectiveness for a percutaneous bone conduction device.

Rational

To date there has been no data collected on the Bonebridge used in adults in NZ. Health care systems differ between countries. Therefore, there is a need to obtain data in the NZ context. The first aim of this study was to obtain clinical outcome data. The second aim of this study was to obtain HRQoL life data.

Methods

Power analysis

The G*Power software program was used to determine the required sample size for this study. The alpha-level was set to 0.5 and effect sizes were determined based on previous research. The total required number of participants was 20 which was determined by sample size analysis.

Ethics Approval

This study obtained ethics approval on 2nd May 2019 from the University of Canterbury Human Ethics Committee (Appendix A). Further, this study was also deemed by the Health and Disability Ethics Committees (HDEC) as being outside the scope of requiring review by HDEC (Appendix B).

Study Design

When evaluating the outcomes of the Bonebridge, this study used patient reported outcome measures to assess HRQoL outcomes, and standard clinical test batteries to assess clinical outcomes. This study used one group of participants receiving the Bonebridge as the

intervention. The participants served as their own control. Demographic data were collected on or before the day of switch-on. Clinical measures were assessed on the day of switch on and at 4 weeks post switch-on. HRQoL questionnaires were collected in a cross-sectional manner at 6 and 12 months post switch-on. This design was selected because it provides a comparison of outcomes before and after an intervention. The limitation of this design is that it does not allow for control of changing factors during the study timeframe (Thiese, 2014). Other interventional study design types such as randomized control trials could not be used with this study because all participants had elected to receiving the intervention as part of their health care and were to be receiving the intervention regardless of participation in the study.

There was a total of four assessment points:

T0 – Demographic data collection and consent process prior to switch on

T1 – clinical assessments at time of switch-on and 4 weeks post switch-on

T2 – patient reported outcome questionnaires at 6 months

T3 – patient reported outcome measures at 12 months.

Participants

Recruitment was conducted solely at the Christchurch Hospital Ear, Nose and Throat (ENT) department. Adults who were receiving medical care by the ENT specialists and had elected to undergo Bonebridge implantation, were invited to participate in the study by the ENT specialist.

Participants must have been 18 years of age or older at the time of recruitment, they must have elected to undergo the Bonebridge implantation procedure, and they must have been able to complete the study questionnaires in the English language. There were no specific exclusion criteria for this study.

Clinical Outcome Measures

Audiometric Thresholds

The objective assessments were completed at an audiology clinic by a New Zealand Audiological Society (NZAS) certified audiologist. Testing was conducted in a sound treated room calibrated to ISO standards. Audiometric equipment included GSI 61 audiometer, 3M 3a insert transducers, the RadioEar B71 bone conductor coupled with a steal tension band, the Telephonics TDH-39 transducer and a sound field loud speaker. The room and all audiometric equipment were within calibration date.

Baseline unaided audiometric thresholds were assessed prior to the implantation surgery. Ear specific air conduction thresholds were obtained at 500, 1000, 2000, 4000, 6000 and 8000 Hz. Bone conductions thresholds were obtained at 500, 1000, 2000 and 4000 Hz. In some cases, a ‘no response’ was recorded on the audiogram at the level of the limit of the audiometer. In those cases, thresholds were entered for data analysis as the limit of the audiometer plus 5 dB. If the threshold was below zero, the measured threshold was recorded on the audiogram. In these cases, the thresholds were entered for data analysis as 0 dB HL. This was consistent with the British Society of Audiology (2011) guidelines. Bone conduction thresholds were obtained at 500, 1000, 2000, and 4000 Hz.

Switch-on took place 2 to 4 weeks post-surgery. The Bonebridge was fitted and adjusted to subjective preference if required. Unaided and aided audiometric thresholds were assessed in the sound-field at 500, 1000, 2000, 4000, and 6000 Hz. The participant was seated with their head position above the calibration floor markers with the loudspeaker at 0 degrees azimuth to their head. Masking was applied when indicated.

Speech Audiometry

At T1, speech discrimination scores (SDS) in quiet were assessed using the Arthur Boothroyd (1968) consonant-vowel- consonant word list recorded from a male speaker in the NZ accent. Participants were mostly tested at three or more intensities to obtain an optimal three-point performance-intensity (PI) function in accordance with the clinic's procedural guidelines. The intensity level at which participants obtained maximum SDS in the unaided and aided condition was compared. This thesis will define maximum SDS as the highest SDS obtained under the condition. This is distinct from a true PI maximum (PIMax) because some participants were not able to obtain a true PIMax under the sound field conditions due to equipment limitations.

Half peak levels (HPLs), mathematically derived from each participants' PI function, were compared in the aided and unaided conditions. The method for deriving HPL using Excel Solver is illustrated in Figure 3. SDS at 50 dB HL (SDS50) in the unaided and unaided conditions were compared. If a PI function lacked a data point at 50 dB HL, the SDS50 was derived using Excel Solver.

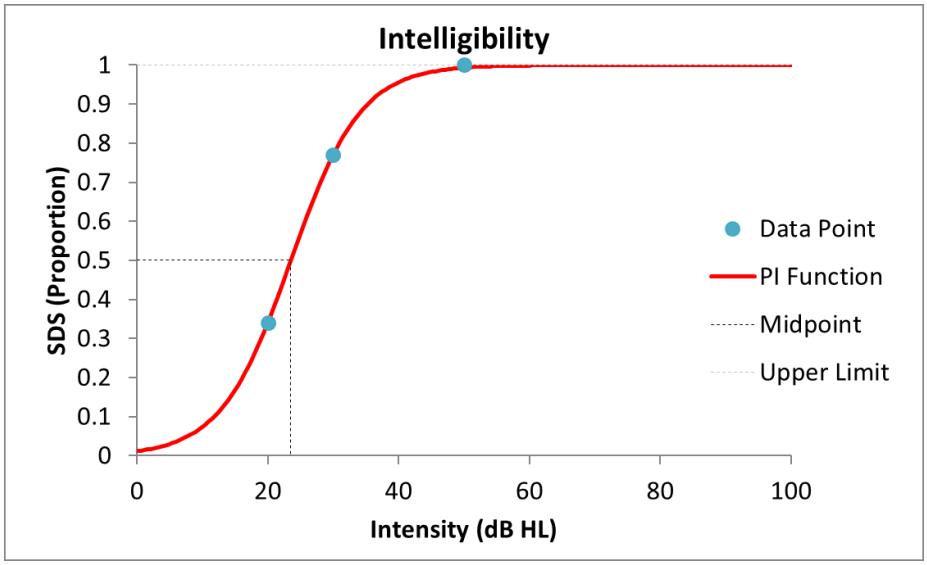

Figure 3. Example of Excel Solver function output for participant 2 in the aided condition. The midpoint provides HPL readout within Excel.

Under the same conditions, speech discrimination in noise was assessed using the Quick Speech-in-Noise Test (QuickSIN; Killion, Niquette, Gudmundsen, Revit, & Banerjee, 2004) and expressed as signal-to-noise ratio (SNR) loss. The same tests were then assessed in the aided state, all in the sound field. A mean was taken from two QuickSIN lists for both the unaided and aided conditions.

Health Related Quality of Life Outcome Measures

Patient reported outcome measures were assessed using pen-and-paper questionnaires that were posted to the participants who then completed them, and return posted them to the University of Canterbury. Measures used to assess the HRQoL benefits of the Bonebridge were the Bone Conduction Device Questionnaire (BCDQ); and the Speech, Spatial, Qualities of hearing Questionnaire 12 Benefit version (SSQ12-B; Noble et al., 2013). HRQoL data were also collected using the Health Utilities Index questionnaire (Horsman et al., 2003).

The BCDQ is an in-house developed questionnaire designed specifically for the Bonebridge (Appendix C). It includes five items covering frequency of use, duration of use, ease of use, and perceived effect the Bonebridge has on vocational performance. This questionnaire was administered at T2 and T3. The SSQ12-B is an abbreviated version of the original SSQ-49. It includes 12 scored questions that enabled the participant to compare perceptions before and after an intervention (Noble et al., 2013). A modified version of the SSQ12-B was administered at T2 and T3. The modification was derived from a previous (unpublished) study's methodology. The response anchors were modified so that "much worse" corresponded to -5 and "much better" corresponded to +5 for every item. Instructions were also modified to include the word "Bonebridge" to provide clarity for participants who also use AC hearing aids.

The HUI is a 15-item questionnaire that can be used to derive multiple measures of a person's health state. One measure is the HUI mark 3 (HUI3) health utility score. HUI3 was selected because it has been shown to be responsive to the effects of hearing aid intervention (Janneke et al., 2007). This questionnaire was administered at 12 months or greater, post switch-on. Permission was obtained from the publisher to modify the wording of questions to include the term "Bonebridge" alongside the term "hearing aids". The HUI3 was administered at T3 and the utility score compared with population normative data

Analyses

Descriptive statics were calculated for demographic data. The original intention for this study was to complete paired means T-tests for pre and post audiometric and speech understanding outcome measures, and for the patient reported outcome measures at T2 and T3. Because these data were not normally distributed, Wilcoxon signed ranks tests were used instead. The statistical analysis was completed using IBM SPSS version 25 software. The HUI3 utility

score was manually calculated using the authors instructions for deriving a multi-attribute level score. The scores were compared with population normative data.

Results

Overview

In this study, it was predicted that Bonebridge recipients would experience improved clinical and HRQoL outcomes following implantation. It was also hypothesized that the HRQoL outcomes would remain consistent from 6-months through to 12-months post implantation. Preliminary analysis of the available data suggests that the Bonebridge provides recipients with significantly improved audiometric thresholds and SDS in quiet. Speech discrimination in noise improved in a statistically significant way. HRQoL measures generally demonstrated improved and consistent HRQoL from 6-months through to 12-months post switch-on.

Demographics

This study included 18 participants, nine male and nine female. The age of participants ranged from 23 to 74 years with a mean age of 44.56 years. Fifteen participants identified as NZ European, two as both NZ European and NZ Māori, and one as NZ. The participants' level of education ranged from early high school level to post-graduate master's degree.

Audiometric Thresholds

The audiometric threshold data were not normally distributed, therefore nonparametric analyses were used. See Figure 4 for mean thresholds. A series of Wilcoxon signed ranks tests revealed that thresholds were significantly improved in the aided condition when compared with the worse ear hearing thresholds for all audiometric frequencies. A Wilcoxon signed Ranks test revealed that the aided condition significantly improved thresholds relative to the better hearing ear at 4 kHz only. See Table 1 for test statistics and p-values.

Table 1 Wilcoxon Signed Ranks Test Statistics and P-Values for the Audiometric Threshold Data.

Frequency	Z (worse ear)	P (worse ear)	Z (better ear)	P (better ear)
500 Hz	-3.625	<.001	-.831	.203
1 kHz	-3.732	<.001	-.527	.299
2 kHz	-3.735	<.001	-.052	.480
4 kHz	-3.685	<.001	-1.945	.026
6 kHz	-3.627	<.001	-1.165	.122

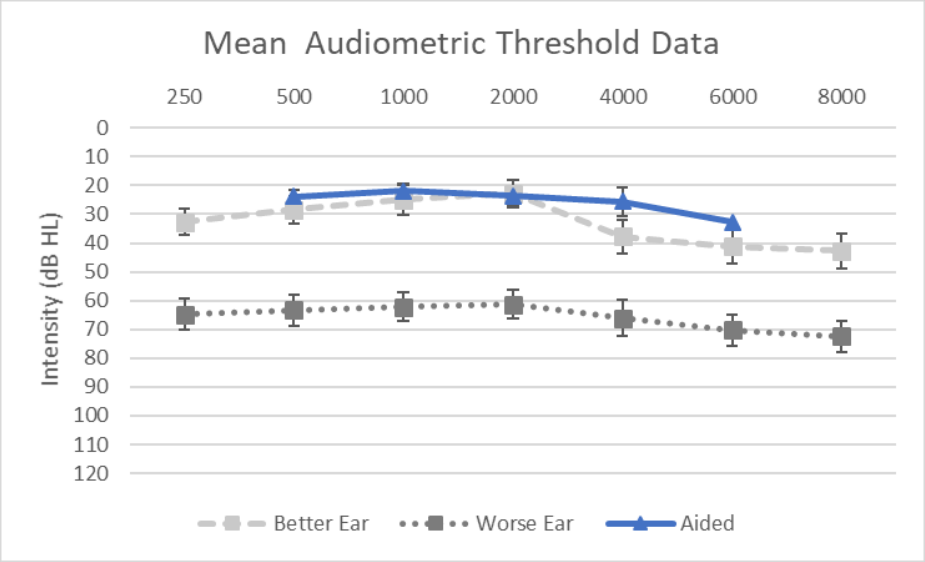

Figure 4. Mean aided and unaided thresholds across audiometric frequencies. Bars indicate one standard error around the mean.

Speech Audiometry

Intensity Level of Maximum Speech Discrimination Score (SDS)

A Wilcoxon signed ranks test revealed that the intensity level at which participants achieved maximum SDS was significantly lower in the aided condition (Median 50) when compared to the unaided condition (Median 60) $Z = -3.511$, $p = < .001$. These data are shown in Figure 5. Three participants achieved maximum SDS at the same intensity for the unaided and

aided conditions. One participant (ID 15) achieved maximum SDS at a higher intensity in the aided condition than in the unaided condition. All other participants improved. Change scores ranged from -5 to 25 dB HL. Mean change score = 9.44 dB HL (SD = 7.45).

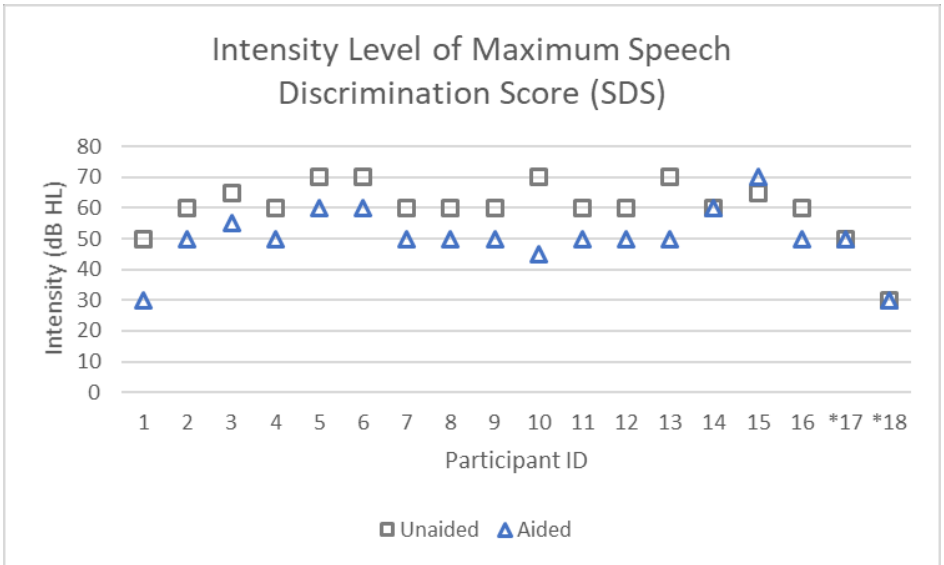

Figure 5. Intensity level at which maximum Speech Discrimination Score (SDS) was achieved under the unaided and aided conditions for each participant.

Half Peak Level (HPL)

The HPLs were derived mathematically as explained in the methods chapter. This technique has limitations that are described in the discussion chapter. A Wilcoxon signed ranks test revealed that the intensity of the half peak levels was significantly lower in the aided condition (Median = 30.5) compared to the unaided condition (Median = 43.5) $Z = -3.727$, $p = < .001$. All participants' HPL improved. Change scores ranged from 1 to 28 dB HL. Mean change score = 13.5 (SD = 8.26). These data are shown in Figure 6.

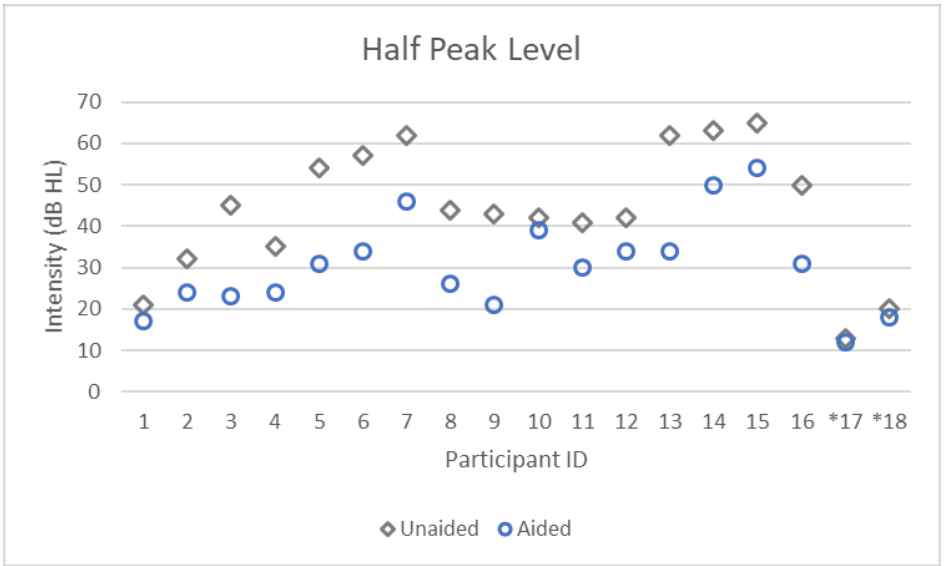

Figure 6. Mathematically derived Half Peak Level (HPL) for each participant.

Speech Discrimination Score at 50 dB HL (SDS50)

A Wilcoxon signed ranks test revealed that the sound field SDS score at 50dB HL (SDS50) was significantly improved in the aided condition (Median = 97) compared to the unaided condition (Median = 71) Z = - 3.409, p = <.001. Three participants had no change. All other participants improved. Change scores ranged from 0 to 86%. Mean change score = 31.06% (SD = 27.39). These data are shown in Figure 7.

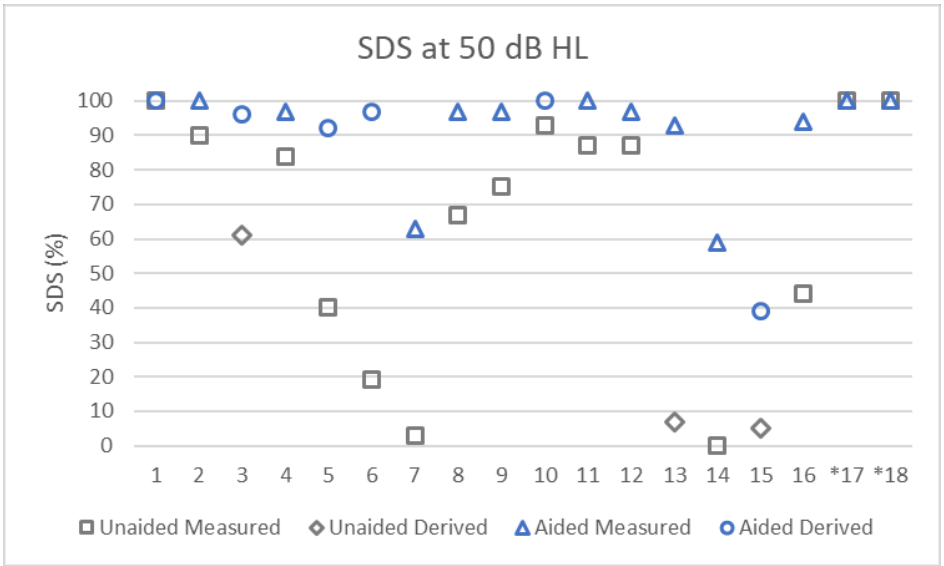

Figure 7. Measured and/or derived Speech Discrimination Score (SDS) at 50 dB HL for unaided and aided conditions for each participant.

Speech discrimination in Noise

The SNR loss as measured by the QuickSIN for each participant is presented in Figure 8. No participants scored in the normal range of 0-2 dB. Using 2 dB as the critical change value, 10 participants experienced an improvement in understanding speech in noise in the aided condition relative to the unaided condition and two participants experienced a decrease in performance in the aided condition. Seven participants' scores did not change by 2 dB. A Wilcoxon signed ranks test revealed that the overall improvement from the unaided condition (SNR Loss Median = 9.25 dB) to the aided condition (SNR Loss Median = 6 dB) was significant statically: $Z = -1.966$, $p = .025$. Mean change score = 3.47 dB (SD = 6.36).

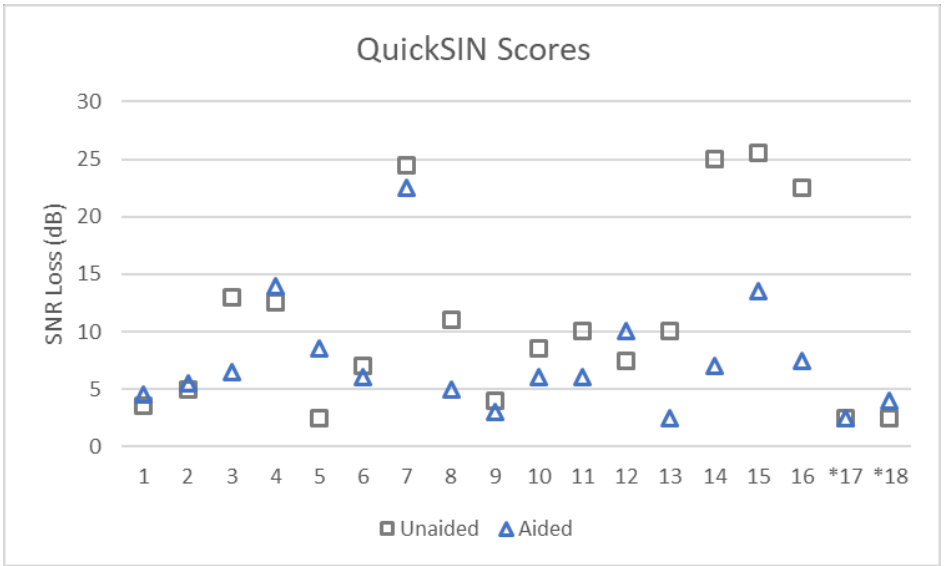

Figure 8. QuickSIN scores expressed as Signal-to-Noise Ratio (SNR) Loss in the unaided and aided condition for each participant.

Health Related Quality of Life

Of the 18 participants, 15 had completed the T2 (6 month) assessment point, and 14 completed the T3 (12 month) assessment point at the time of data analysis. While the post implant data collection are ongoing, the data collected to date were analyzed for this thesis. Those preliminary results are described in the following sections. BCDQ data were available for the 15 participants at T2 and for 14 participants at T3.

Bone Conduction Device Questionnaire

Usage

At T2, 11 participants reported using the Bonebridge 7 days a week, two reported using it five days and two reported using it four days. Seven participants reported using the Bonebridge for 12-16 hours per day; one participant for 8-12 hours; three for 4-8 hours; two for 2-4 hours, and; one participant for more than 16 hours per day. Thirteen participants exclusively use the Bonebridge. Two participants use the Bonebridge along with another type of hearing aid.

Participants reported using the Bonebridge a median of 7 days a week at both T2 and T3 (Z = .000, p = 1.000). At T3, the median hours of Bonebridge use per day corresponded to 12-16 hours per day. A Wilcoxon signed ranks test revealed this did not differ significantly from T2 (Z = -1.000, p = .317).

Ease of use

Figures 9 and 10 illustrate the ease of use data for the study participants. At both 6-months and 12-months post switch-on, all participants reported the Bonebridge was easy or very easy to mount. Similarly, most participants reported that changing the volume and the batteries was easy or very easy. A Wilcoxon signed ranks test revealed participant responses were not significantly different at T2 and T3 (Z = -1.000, p = .317).

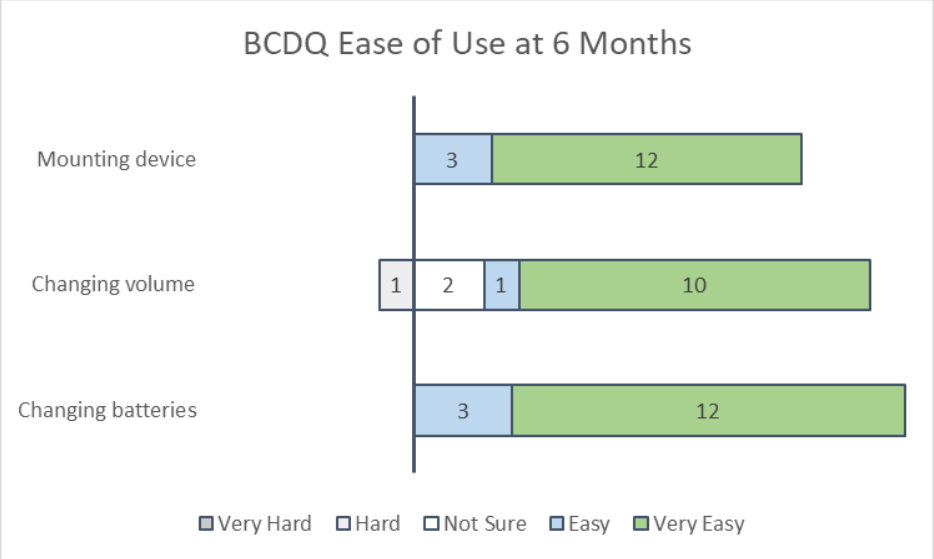

Figure 9. Bone Conduction Device Questionnaire (BCDQ) ease of use question responses at 6 months (T2).

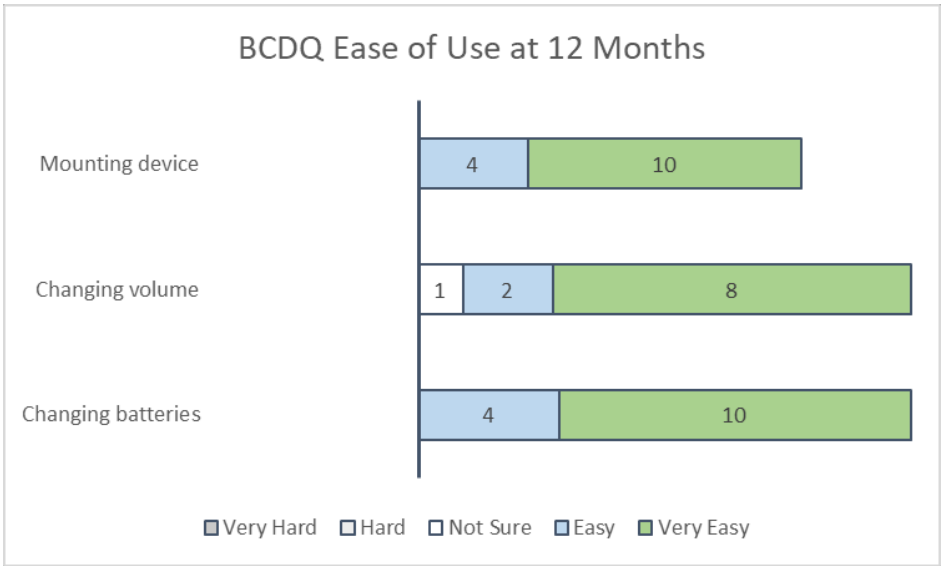

Figure 10. Bone Conduction Device Questionnaire (BCDQ) ease of use question responses at 12 months (T3).

Vocational performance

Participants had the option to mark the vocational performance questions as non-applicable. These data are shown in Figures 11 and 12. Of the 15 participants who completed the questionnaire at 6-months, 12 participants responded to the vocational performance questions. Most of the participants (N = 9, 75%) reported that they either strongly agree or agree that the Bonebridge causes them to perform better at work. Most participants (N = 8, 66.7%) either strongly agreed or agreed that the Bonebridge causes them to be more productive. Half of the participants (N = 6, 50%) either strongly agreed or agreed that the Bonebridge causes them to miss fewer days at work. Most participants (N = 9, 75%) either strongly agreed or agreed that the Bonebridge causes them to have less stress at work. Half of the participants (N = 6, 50%) either strongly agree or agree that the Bonebridge causes them to be less tired at work. A Wilcoxon signed ranks test revealed that there were no significant changes in perceived vocational

performance at 12 months compared with 6 months post switch-on. See Table 2 for statistics and P-values.

Table 2 Wilcoxon Signed Ranks Test Statistics and P-Values for Bone Conduction Device Questionnaire (BCDQ) Vocational Questions.

Question	Z	P
Performance	-1.342	.180
Productivity	-.447	.655
Missed days	.000	1.000
Stress	-.447	.655
Tiredness	-1.414	.157

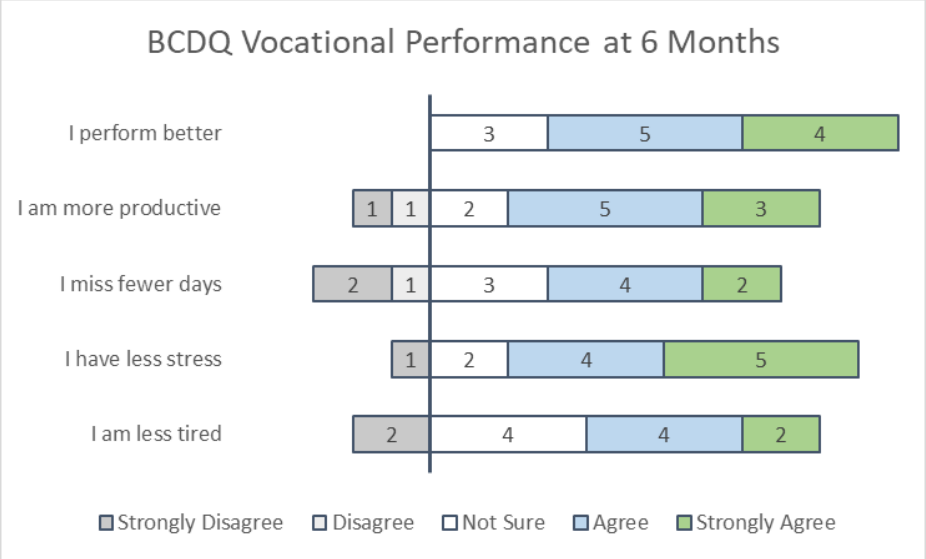

Figure 11. Bone Conduction Device Questionnaire (BCDQ) vocational performance question responses at 6 months (T2).

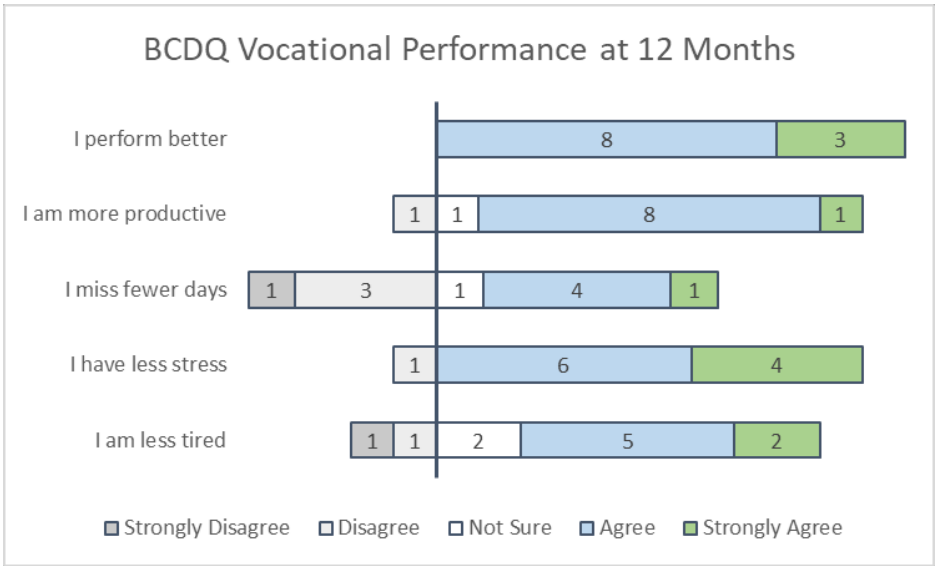

Figure 12. Bone Conduction Device Questionnaire (BCDQ) vocational performance question responses at 12 months (T3).

SSQ12-B

The SSQ12-B was completed by 15 participants at 6 months and by 14 participants at 12 months. However, one participant incorrectly filled out the questionnaire at the 12-month assessment point and that participant's data were removed from the analyses. Subsequently there are data for only 13 participants at the 12-month assessment point. The data were not normally distributed, and a non-parametric approach was used to test the study hypotheses.

Figures 13, 14 and 15 show the SSQ-B at 6-months and 12-months post switch-on. The data indicate benefit (positive scores) following Bonebridge implantation. A Wilcoxon signed ranks test revealed no significant change in benefit from the 6-month to the 12-month assessment (Z = -1.569, p = .117). This pattern of benefit was seen for all SSQ12-B items with exception of item 8 (ability to detect whether a source of a sound is getting closer or further away). For this item, participants benefit decreased significantly from 6- to 12-months post-implantation (Z = -2.393, p = .017)

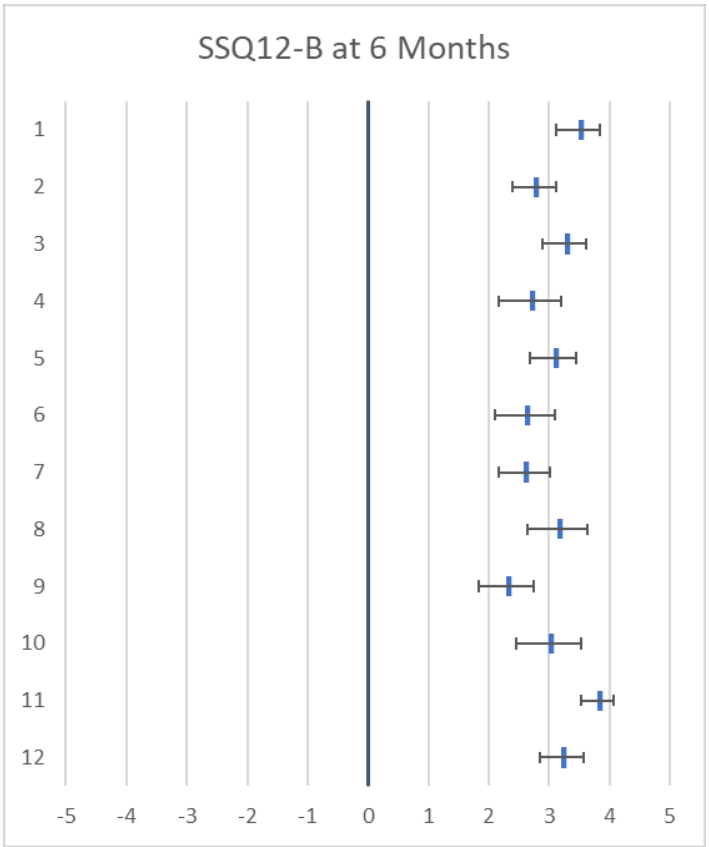

Figure 13. 6-month Speech, Spatial and Qualities of Hearing (SSQ)12-B mean score by item. Bars indicate 1 standard error around the mean.

Note: For figures 13 and 14, the question subscales are as follows: Speech in noise – item 1, 3, and 4; Multiple speech streams – item 2 and 5; Localization – item 6; Distance and movement – item 7 and 8; Segregation – item 9; Identification of sound – item 10; Quality and naturalness – item 11; and, Listening effort – item 12.

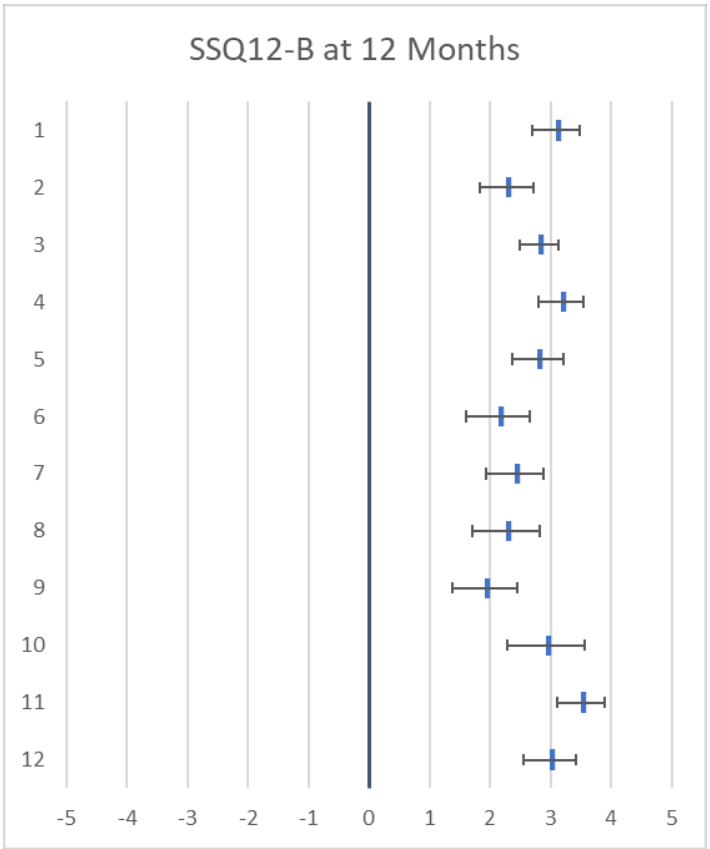

Figure 14. 12-month Speech, Spatial and Qualities of Hearing (SSQ)12-B mean scores by item. Bars indicate 1 standard error around the mean.

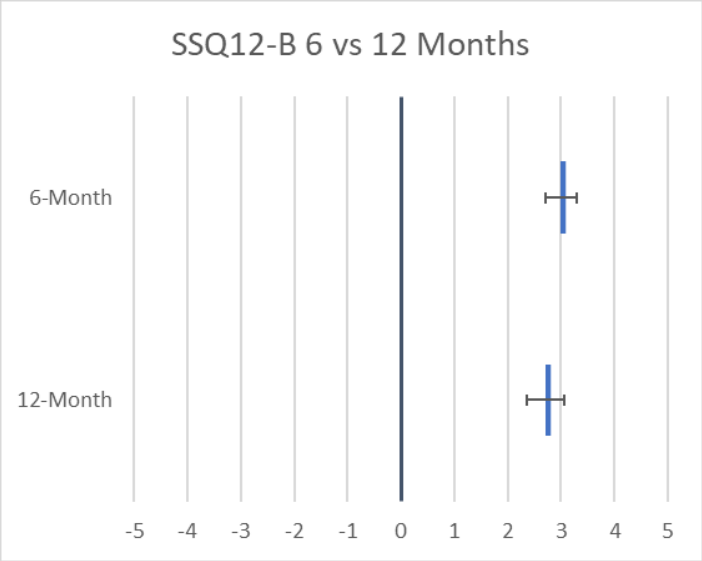

Figure 15. Total Speech, Spatial and Qualities of Hearing (SSQ)12-B scores at 6 and 12 months compared. Bars indicate 1 standard error around the mean.

Health Utilities Index Mark 3 (HUI3)

Six participants completed the HUI questionnaire at around 12 months post switch-on. These data were used to derive HUI3 utility scores. These data are shown in Table 3. The data indicate that some participants have higher utility scores than the control population, while others have lower utility scores.

Table 3 Health Utility Index Mark 3 (HUI3) utility and control scores for study participants

Participant ID	Utility Score	Control
2	.42	.77
4	.67	.89
7	.85	.85
10	.78	.72
11	.40	.85
18	.79	.85

Note: Control data from 2006 Australian population summary statistics, age matched.

Discussion

Overview

The Bonebridge is a relatively new device that overcomes some of the limitations associated with conventional bone conduction devices. Previous studies show positive objective and subject outcomes. A systematic review by Magele, Schoerg, Stanek, Gradl, and Georg Mathias (2019) looking at 39 studies reported positive objective and subjective outcomes following Bonebridge implantation. The aim of this study was to determine to what extent the Bonebridge improves clinical and HRQoL outcomes in the NZ context through audiological assessments and patient reported outcome measures. The preliminary results suggest that the Bonebridge improved clinical outcomes in participants, and that participants perceived an improvement in HRQoL at 6 and 12 months post switch-on.

Audiometric Thresholds

The aim of this assessment was to determine if the Bonebridge provided participants with improved audiometric thresholds. The preliminary results of this study suggest that the Bonebridge does provide participants with improved audiometric thresholds, particularly when comparing aided thresholds with the worse ear thresholds. This means that participants have improved access to sound across tested frequencies. The mean threshold data (Figure 4) is taken from all participants of which have a range of hearing loss configurations. Within the sample there are participants with bilateral CHL, unilateral CHL, MHL and SSD. The Bonebridge was implanted on the side of the worse ear. Therefore, the finding that aided thresholds are not significantly better than unaided better ear thresholds at all frequencies was expected. In other words, it was expected that less improvement would be measured in the aided state if the person had normal hearing in their better ear. The protocols of this study were developed during the

early stages of Bonebridge research. One other study by Rahne et al. (2015) used ear specific thresholds prior to surgery and compared them to aided sound field thresholds. They reported significant improvements. Most other Bonebridge literature used unaided and aided sound field thresholds after surgery to measure functional hearing gain. They measured significant improvement in audiometric thresholds for the Bonebridge (Ngui & Tang, 2018; Oh et al., 2019; Riss et al., 2014; Schmerber et al., 2017; Skarżyński et al., 2019; Weiss et al., 2017).

Speech Discrimination

The aim of these assessments was to determine if the Bonebridge provided participants with improved speech discrimination in quiet. The preliminary results of these assessments suggest that it does.

Level of Maximum SDS

The preliminary results indicate that no participant's level decreased significantly, and most experienced improvement in the level at which they were able to obtain the maximum SDS with the AB word list. This provides evidence of an improvement in the audibility of speech. This finding is in line with Schmerber et al. (2017) who reported improved change scores of 16 to 19 dB. The exceptions to this were participants 14, 15, 17 and 18 where the difference in intensities for the unaided and aided maximum SDS were not clinically significant. The reasons for this occurring in participants 14 and 15 are not known. Participants 17 and 18 likely did not realize improvement because both had SSD indications.

Half Peak Level

The key finding of the preliminary results was that all participants' HPL improved in the aided condition. This provides further indication that in a clinical environment, all participants had improved audibility of speech. For some participants, audibility was minimally improved

while for other participants, audibility was greatly improved. A search of the relevant literature indicated that using HPLs to compare audiological outcomes in the unaided and aided conditions has not been used in previous studies.

SDS50

The key finding for this measurement was that participants' SDS at 50 dB HL, a quiet conversation level, was significantly improved in the aided condition. This indicates that most participants experienced an improved understanding of speech at this level. Some participants experienced the ceiling effect. No participants' understanding decreased. This outcome is consistent with other studies who also measured improved speech discrimination at set intensity levels (Eberhard et al., 2016; Gerdes, Salcher, Schwab, Lenarz, & Maier, 2016; Oh et al., 2019; Rahne et al., 2015; Riss et al., 2014; Schmerber et al., 2017; Skarżyński et al., 2019; Weiss et al., 2017). It must be noted that each of the above-mentioned studies either used different intensities or measured it in Sound Pressure Level.

SNR Loss

The QuickSIN measurement produced variation in scores unaided and aided as well as in the change scores. Most participants' scores did improve, indicating improved ability to understand speech in noise. It is worth noting that some participants experienced no critical change and two had poorer scores in aided condition. The overall improvement in ability to understand speech in noise is generally consistent with other studies. However, other studies found stronger results.

A thorough search of relevant literature revealed that this was the only other study to use QuickSIN for measuring Bonebridge outcomes. Kulasegarah et al. (2018) measured a significant improvement in SNR Loss among four participants from an unaided range of 3.7-10.5 to aided

0.2-1.2 SNR Loss using an unspecified combination of the QuickSIN and Bench-Kowal-Bamford (BKB; Bench, Kowal, & Bamford, 1979) speech in noise test. Other studies commonly used mono or disyllabic word lists with noise presented simultaneously to obtain a word score or SRT measured as Db SNR. Skarżyński et al. (2019) reported improved SRTs in noise from median 12.8 dB SNR to median -1.1 dB SNR using a Polish Sentence test with noise presented at 0 degrees azimuth. Weiss et al. (2017) also reported improved SRTs from -3.8 dB SNR to -5.2 dB SNR. Schmerber et al. (2017) reported significant improvement in scores from an average 62% to 89% using the French language dissyllabic words (Fournier, 1951) with noise presented simultaneously at 180 degrees azimuth. Ihler, Volbers, Blum, Matthias, and Canis (2014) reported improved speech scores from average 8.3% to 37.5% using the German language Freiburg Monosyllabic Test (Hahlbrock, 1953) with speech weighted noise presented simultaneously. Oh et al. (2019) also measured a significant improvement in scores measured with a Korean monosyllabic word list with noise presented simultaneously at 0 degrees azimuth. Finally, Rahne et al. (2015) report significantly improved SNR measured using the SRT of sentences in noise. A possible reason for the current studies SNR Loss results not being as strong as those of other studies may be because SNR Loss was tested 1-month post switch on. A longer time frame may allow for more thorough acclimatization and potentially improve SNR Loss outcomes to a greater extent.

Bone Conduction Device Questionnaire

The aim of administering the BCDQ was to obtain self-reported information on frequency and duration of usage, perception of ease of use, and perception of vocational performance improvements obtained through use of the Bonebridge. Most participants reported using the Bonebridge 7 days a week for 12-16 hours/day. This is a reasonable indication that

participants liked the device and perceived benefit in using it. These results are consistent with Schmerber et al. (2017) who reported that 11 out of 12 participants used their Bonebridge for the whole day as measured using the IOI-HA. This and the current studies reported amount of frequency and duration of usage is higher than found by Eberhard et al. (2016) who, using their own frequency and duration questionnaire, reported an average use of 5.5 days/week with 50% of participants using the device for 8 hours or more per day.

This study also sought to obtain information on ease of use and vocational outcomes with the Bonebridge. Almost all participants reported that the Bonebridge is easy to use in terms of correct mounting, changing volume and changing batteries. Further, participants perceived that the Bonebridge did improve vocational performance. A thorough search of the relevant literature revealed that no other study has assessed self-reported vocational outcome data with the Bonebridge. It must also be noted that the BCDQ was developed in-house therefore the findings are not directly comparable to other studies.

SSQ12-B

The key finding of this outcome measure was that, overall, participants reported that the Bonebridge provided benefit in speech, spatial and qualities of hearing. This translates to an improved ability to understand speech in the presence of competing noise, receive multiple sources of speech, and to correctly localize sounds (Gatehouse & Noble, 2004). A literature search revealed that the SSQ12-B (short form) has likely not been used in any studies with the Bonebridge. However, one study by Laske et al. (2015) measured outcomes with the SSQ-B (full version) on nine participants with SSD. Overall, their participants found good benefit in the speech domain, and some benefit in the spatial and quality domains. Because the SSQ-B correlates with the SSQ12-B (Noble et al., 2013), it can be inferred that the current study

achieved stronger results in the spatial and quality domains than those of Laske et al. (2015). This is likely a reflection of the current study's larger sample size and make-up of predominantly CHL and MHL.

Health Utilities Index

The HUI function is derived from multiple health attribute level scores. Therefore, scores that are lower than control should not be solely attributed to Bonebridge implantation. Further, the small sample size of the current study does not allow a conclusion to be made. Future studies should obtain before and after HUI function scores to obtain HRQoL data that is more sensitive to Bonebridge implantation. Such data could be used to calculate the cost effectiveness of the Bonebridge. A literature search revealed that no other study has yet obtained HUI3 utility data but a study by Vickers et al. (2018) plans to use HUI2 and 3 to obtain data with the Bonebridge.

SSD Indication

Included in the results are data from two SSD participants indicated by the asterisk in the figures in the results chapter. These participants belong to a different clinical subpopulation whose condition can also be managed with the Bonebridge. Persons with SSD lack binaural input, resulting in reduced sound localization and SNR performance (Agterberg, Hol, Van Wanrooij, Van Opstal, & Snik, 2014; Harford & Dodds, 1966). Management options normally aim to eliminate or reduce the head shadow effect (Harford & Dodds, 1966; Hol et al., 2010). However, the audiological outcomes measured in the current study did not specifically assess for benefit to SSD participants. This is likely the reason that SSD participants did not experience significant improvement in audiological outcomes. However, SSD participants generally reported improved HRQoL outcomes.

Other studies have incorporated directionality when testing speech discrimination in noise with the Bonebridge. Salcher, Zimmermann, Giere, Lenarz, and Maier (2017) reported significant improvement in all tested directional scenarios. Laske et al. (2015) and Schmerber et al. (2017) reported statistically significant improvements when the signal was presented on the side of the Bonebridge.

Indeed, CIs remain the only possibility to restore binaural hearing effect in persons with SSD (Agterberg et al., 2014). CIs and implantable bone conduction devices both incur surgery related costs. Therefore, cost-effectiveness analysis should inform future decisions when considering management options for SSD.

Limitations and Future Research

The study has limitations that are inherent to field research. Clinical outcome data was collected in a clinical environment by multiple clinicians. Further, patient reported outcome measures were completed by participants in their natural environment using pen and paper. This contrasts with research conducted in a lab were the research is main effort and the researchers can more closely control test conditions to achieve consistency

Mathematically deriving HPLs carries the limitation that an assumption must be made as to whether each participant is able to attain a PIMax of 100%. Further, a limitation associated with the audiometric thresholds is that unaided thresholds were measured prior to surgery using ear specific transducers, while aided thresholds were measured on the day of switch-on in the sound field. This method does not account for possible deterioration in hearing loss as a result of surgery, or the for the potential differences as a result of binaural summation that may be present in the aided condition. Comparison is therefore not direct. This study attempted to mitigate this

limitation by including half peak level measurements which are commonly used to cross-check audiometric thresholds.

It is suggested that future studies measure unaided ear specific PTA both before and after surgery to determine if a hearing loss had deteriorated since the time of surgery. It is also suggested that future studies measure both unaided and aided sound field thresholds at the same assessment point post switch-on.

Conclusions

The aim of these assessments were to determine to what extent the Bonebridge improves clinical and HRQoL outcomes in the NZ context. The key findings were that the Bonebridge provided participants with significant benefit in both clinical and HRQoL outcomes. Benefit was not measured to be as strong with speech discrimination in noise. Future studies will be needed to verify the true degree of benefit in comparison to other interventions.

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UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 369 4588, Extn 94588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2019/06/LR

2 May 2019

Eliot Healy
Psychology, Speech and Hearing
UNIVERSITY OF CANTERBURY

Dear Eliot

Thank you for submitting your low risk application to the Human Ethics Committee for the research proposal titled "Health-Related Quality of Life Following Bonebridge Implantation".

I am pleased to advise that this application has been reviewed and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your email of 30th April 2019.

With best wishes for your project.

Yours sincerely

pp. R. Robinson

Professor Adrian Sawyer
Deputy Chair, Human Ethics Committee

Health and Disability Ethics Committees

Appendix B

Health and Disability Ethics Committees
20 Aitken Street
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0800 4 ETHICS
hdecs@moh.govt.nz

Monday, 11 April 2016

Dr Melanie Souter
Otolaryngology Department
5th Floor Riverside
Christchurch Hospital
Riccarton Avenue
Private Bag 4710

Dear Dr Souter,

Study title:	Health-Related Quality of Life Following Bonebridge Implantation

Thank you for emailing HDEC a completed scope of review form on 01 April 2016. The Secretariat has assessed the information provided in your form and supporting documents against the Standard Operating Procedures.

Your study will not require submission to HDEC, as on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.

This study involves participants who meet the criteria for Bonebridge implantation and will assess their quality of life before and after implantation. This is not an intervention study and the implantation of this device will not be in any way controlled or determined by participation in this study. These participants will be recruited by their surgeon who will be informed of the research and will not be accessing participants' health information for the purpose of recruitment. Participants are not considered vulnerable and will provide informed consent to participate in this study before their health information is accessed and will not have any tissue used or collected.

An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).

For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:

- one or more participants who will not have given informed consent to participate, or
- one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study), or
- standard treatment being withheld from one or more participants, or
- the storage, preservation or use of human tissue without consent, or
- the disclosure of health information without authorisation.

If you consider that our advice on your project being out of scope is in incorrect please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application, but may be used as evidence that HDEC review is not required for it.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Please don't hesitate to contact us for further information.

Yours sincerely,

Fox Swindells
Advisor
Health and Disability Ethics Committees
hdecs@moh.govt.nz

Appendix C

Bone Conduction Device Questionnaire (BCDQ) Date: _____

Please answer each question to the best of your ability

1. Around how many days a week do you use your Bonebridge? (please tick one box)

☐ I do not use it (0)	☐ 4 days
☐ 1 day	☐ 5 days
☐ 2 days	☐ 6 days
☐ 3 days	☐ 7 days

2. Around how many hours each day do you use your Bonebridge? (please tick one box)

☐ I do not use it (0)	☐ 8 – 12 hours
☐ Less than 2 hours	☐ 12 – 16 hours
☐ 2 – 4 hours	☐ More than 16 hours
☐ 4 – 8 hours	☐ I don't know

3. Do you use any other type of hearing aid? ☐ Yes ☐ No

   If yes, what type of aid do you use? _____

4. How well can you care for your Bonebridge (please tick one box for each task)?

	Very easy	Easy	Not Sure	A little hard	Very hard
Mounting device					
Changing volume					
Changing batteries					

5. How has the Bonebridge affected your work (please tick one box for each line)? If you do not work, please leve this table blank.

	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
I perform better					
I am more productive					
I miss fewer days					
I have less stress					
I am less tired					